

DETAILED ACTION

This action is responsive to communication filed 1/27/2012.

Any rejection(s) and/or objection(s) not reiterated herein have been withdrawn.

To allow entry of the rejections below, this action is made non-final.

It is noted that while searching for the elected species, additional art was found that read on the claims. This should not be construed that the full scope of the claims was examined.

Information Disclosure Statement

The IDS was fully considered and is attached.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito (EP 1306671-cited by IDS) in further view of Aoyagi (EP 0967484-cited by the IDS) and Shah (US Patent 6727092-previously cited).

The claims are directed to (in part): a method comprising the steps of:

1. treating the sample with a treating agent containing:
 - a. an acidifying agent, and
 - b. a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule;
2. reacting the sample treated in step 1 with a probe that binds to the HCV antigen; and
3. determining if the HCV antigen binds to the probe.

Saito discloses a method of pretreatment of a sample using a pretreating fluid containing a cationic surfactant and an organic acid for the detection of a virus, including HCV; see abstract and para. [0007] and [0008]. The author describes using various organic acids, including citric and acetic acids; see Table 3, para. [0021] and instant claim 5. The author also describes using a probe or an antibody to measure viral antigen following pretreatment; see para. [0023].

While Saito describes using various surfactants, including cationic surfactants, Saito does not explicitly describe using a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule, such as, decyltrimethylammonium chloride; see instant claim

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7. Saito does not disclose the use of a hydrochloric acid; see instant claim 5 (elected species). Saito does not teach using a decyltrimethylammonium bromide; see claim 5 (elected species).

Aoyagi teaches a method comprising treating a sample comprising HCV with various treatment solutions for HCV detection. The author describes using multiple cationic surfactants, including those having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule, such as decyltrimethylammonium chloride; see Table 10 and instant claim 7. The author discloses that such surfactant "causes an increase in detection sensitivity in HCV-positive sera"; see para. [0168]. Aoyagi teaches the use of hydrochloric acid in a composition comprising a surfactant in the pretreatment of a sample.

Shah teaches using a surfactant to remove the lipid envelope of HCV, thereby exposing the HCV core protein to solution; see col. 27, lines 55+. Shah specifically discloses using the surfactant, dodecyltrimethylammonium bromide, in compositions for detecting HCV antigen; see Table VII, col. 30.

It would have been obvious to one of ordinary skill in the art to use decyltrimethylammonium chloride as a cationic surfactant in the pretreatment method taught by Saito. One would have been motivated to do so because Aoyagi teaches that the addition of such surfactant causes an increase in detection sensitivity in HCV-positive sera.

It would have been obvious to use HCl as acid in the pretreatment method taught by Saito. One would have been motivated to do so because HCl has been shown to be

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used in pretreatment compositions for detecting HCV in a sample (the same field of endeavor). Also see MPEP 2144.06 for "SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE".

It would have been obvious to one of ordinary skill in the art to use the bromide salt form of dodecyltrimethylammonium in the method taught by Saito and Aoyagi. One would have been motivated to do so because dodecyltrimethylammonium bromide has been shown to be used in compositions for detecting HCV in a sample (the same field of endeavor). Also see MPEP 2144.06 for "SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE".

There would have been a reasonable expectation of success given the underlying materials and methods are widely known and commonly used as evidenced by the prior art (*e.g.* use of surfactants and acids for HCV detection, etc.).

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art.

Because Saito and Aoyagi describe the same steps using the same composition, the same results must occur as instantly claimed (*i.e.* the release of the HCV antigen and the interaction of antibodies that bind to the HCV antigen). Also see MPEP 2112.01 II COMPOSITION CLAIMS-IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES.

Response to Arguments

Applicant's arguments with respect to claims 4, 5 and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE S. HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHELLE S HORNING/
Examiner, Art Unit 1648